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FIRST NAMED INVENTOR FILING DATE ATTORNEY DOCKET NO. APPLICATION NO. J **TSCHOPP** A049 US 09/520,489 03/08/00 **EXAMINER** HM22/0313 CANELLA JAMES F. HALEY, JR. PAPER NUMBER **ART UNIT** C/O FISH AND NEAVE 4 1251 AVENUE OF THE AMERICAS NEW YORK NY 10020 1642 **DATE MAILED:** 03/13/01

Please find below and/or attached an Office communication concerning this application or proceeding.

**Commissioner of Patents and Trademarks** 



## Office Action Summary

Application No. 09/520,489 Applicant(s)

Examiner

Group Art Unit

Tschopp

Responsive to communication(s) filled on		Karen Canella	1642		
Since this application is in condition for allowance except for formal matters, in accordance with the practice under Ex parte Quay#835 C.D. 11, 453 O.G. 213.  A shortened statutory period for response to this action is set to expire	Responsive to communication(s) filed on				
In accordance with the practice under Ex parte QuayNe35 C.D. 11; 453 O.G. 213.  A shortened statutory period for response to this action is set to expire	☐ This action is <b>FINAL</b> .				
longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).  Disposition of Claim  \[ \times Claim(s) \frac{1.42}			on as to the m	erits is closed	
Claim(s) 1-42   is/are pending in the applicat   Of the above, claim(s)   is/are withdrawn from consideration   Claim(s)   is/are allowed.     Claim(s)   is/are epected.     Claim(s)   is/are objected to.     Claim(s)   is/are objected to restriction or election requirement.     The drawing(s) filed on   is/are objected to by the Examiner.     The proposed drawing correction, filed on   is/are objected to by the Examiner.     The proposed drawing correction, filed on   is/are objected to by the Examiner.     The oath or declaration is objected to by the Examiner.     The oath or declaration is objected to by the Examiner.     The oath or declaration is objected to by the Examiner.     Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).	longer, from the mailing date of this communication. Failure application to become abandoned. (35 U.S.C. § 133). Exten	to respond within the period for re	esponse will ca	use the	
Of the above, claim(s)	Disposition of Claim				
Claim(s)	X Claim(s) <u>1-42</u>		is/are pend	ling in the applicat	
Claim(s)	Of the above, claim(s)	is	s/are withdrawn	from consideration	
Claim(s)	Claim(s)	· · · · · · · · · · · · · · · · · · ·	is/ar	e allowed.	
Application Papers  See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.  The drawing(s) filed on	Claim(s)		is/ar	e rejected.	
Application Papers  See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.  The drawing(s) filed on	Claim(s)		is/are	e objected to.	
See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.  The drawing(s) filed on	X Claims <u>1-42</u>	are subject to	restriction or el	ection requirement.	
<ul> <li>Notice of References Cited, PTO-892</li> <li>☐ Information Disclosure Statement(s), PTO-1449, Paper No(s).</li> <li>☐ Interview Summary, PTO-413</li> <li>☐ Notice of Draftsperson's Patent Drawing Review, PTO-948</li> </ul>	□ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.  □ The drawing(s) filed on is/are objected to by the Examiner.  □ The proposed drawing correction, filed on is □ approved □ disapproved.  □ The specification is objected to by the Examiner.  □ The oath or declaration is objected to by the Examiner.  Priority under 35 U.S.C. § 119  □ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).  □ All □ Some* □ None of the CERTIFIED copies of the priority documents have been □ received.  □ received in Application No. (Series Code/Serial Number) □ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).  *Certified copies not received:				
SEE OFFICE ACTION ON THE FOLLOWING PAGES	<ul> <li>Notice of References Cited, PTO-892</li> <li>☐ Information Disclosure Statement(s), PTO-1449, Papel</li> <li>☐ Interview Summary, PTO-413</li> <li>☐ Notice of Draftsperson's Patent Drawing Review, PTO-</li> <li>☐ Notice of Informal Patent Application, PTO-152</li> </ul>	948			

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## **DETAILED ACTION**

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## Election/Restriction

- 1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-11 and 28, drawn to nucleic acids encoding APRIL ligand, vectors, host cells thereof and the expression of recobinant protein, classified in class 536, subclass 23.5 and class 435, subclasses 69.1 and 320.1.
  - II. Claims 12-17, drawn to APRIL polypeptides and pharmaceutical compositions thereof, classified in class 514, subclass 2.
  - III. Claims 19-21, drawn to antibodies that bind to APRIL ligand polypeptides, classified in class 424, subclass 130.1.
  - IV. Claims 22-25, drawn to methods for preventing or reducing the severity of an autoimmune disease, and methods for preventing or reducing the severity of an immune response to a tissue graft comprising the administration of APRIL ligand polypeptides, classified in class 530, subclass 300.
  - V. Claims 26 and 41 and 42 in part, drawn to methods for treating cancer and a method for supressing the growth of a tumor cell comprising the administration of APRIL ligand polypeptides, classified in class 530, subclass 300. Claims 41 and 42 will be examined with this group to the extent that they read on the administration of APRIL ligand polypeptide.
  - VI. Claim 27, drawn to a method of identifying a receptor for APRIL comprising detecting the binding of a labeled APRIL or a labeled APRIL fragment with a receptor, classified in class 435, subclass 7.2.
  - VII. Claims 29-31, drawn to methods for treating a disorder related to APRIL in a mammal comprising introducing a vector comprising APRIL and expressing APRIL in the mammalian cell, classified in class 514, subclass 44.

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VIII. Claims 32-35, drawn to methods for inducing cell death and methods of treating, supressing, activating or altering an immune response comprising the administration of an agent capable of interfering with the binding of APRIL to a receptor, classified, for example, in class 530, subclass 387.1.

- IX. Claims 36-40 and 41 and 42 in part, drawn to methods of treating, suppressing or altering the progression of cancer and methods for suppressing the growth of a tumor comprising administering a blocking agent between APRIL ligand and its receptor capable of interfering with the association, classified, for example, in class 530, subclass 387.1. Claims 41 and 42 will be examined with this group to the extent that they read on the administration of antibodies.
- 2. The inventions are distinct, each from the other because of the following reasons:

Inventions of Groups I, II and III are structurally and functionally different products which are made by different methods and have different uses. The examination of all groups would require different searches in the U.S. Patent Shoes and the scientific literature and would require the consideration of different patentability issues.

The methods of Groups IV-IX differ in the method objectives, method steps and parameters and in the reagents used.

Inventions II and IV are related as product and process of use. Inventions II and V, as well as Inventions II and VI are also related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptides of Invention II are used in the different methods of Inventions IV, V and VI. Furthermore, the polypeptides of Invention III can be used to raise the antibodies of Invention III.

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Inventions III and VIII are related as product and process of use. Inventions III and IX are also related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibody of Invention III is used for the distinct methods of Inventions VIII and IX. Furthermore, the antibodies of Invention III can be used in an in vitro diagnostic assay and in a method of making anti-idiotypic antibodies.

Inventions I and VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the nucleic acids of invention I can be used in an in vitro mutagenesis assay..

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and recognized divergent subject matter and because the searches required for the groups are not co-extensive, restriction for examination purposes as indicated is proper.

- 3. Because of the complexity of the claims, telephonic restriction was not attempted.
- 4. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

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5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Canella whose telephone number is (703) 308-8362. The examiner can normally be reached on Monday through Friday from 8:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703) 308-3995. Any inquiry of a general nature or relating to the status of this application or proceeding should be

directed to the Group receptionist whose telephone number is (703) 308-0196.

Karen A. Canella, Ph.D.

Patent Examiner, Group 1642

March 12, 2001

and []

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